

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: DING *et al.*

Group Art Unit: To be assigned

Serial No.: To be assigned

Examiner: To be assigned

Filed: February 4, 2002

Attorney Docket No.: 10177-110-999

For: DRUG RELEASE STENT
COATING

Continuation of Application Serial No.
09/012,443 filed January 23, 1998

PRELIMINARY AMENDMENT UNDER 37 C.F.R § 1.115

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please enter the following Preliminary Amendment and remarks into the file
of the above-identified application.

In the Title:

Please amend the title as follows:

In the title please delete "PROCESS".

In the Abstract:

Please amend the abstract as follows:

In the title of the abstract, please delete "BACKGROUND OF THE
INVENTION" and replace with --ABSTRACT--.

In the Specification

Please amend the specification as follows:

On page 1, line 4, after "The present application is", please insert -- a
continuation of application serial no. 09/012,443 filed January 23, 1998, which is a divisional
of application serial no. 08/663,490 filed June 13, 1996 now U.S. Patent No. 5,837,313 which
is--.

On page 1, line 10, please delete "08/_____" and replace with -- 08/663,518 --.

On page 6, line 20, please replace "finally" with -- finely --.

On page 9, line 25, please insert -- (ethylene-propylene terpolymer) -- after "EPDM".

On page 10, line 17, please delete "Elgiloy® and Phynox®" and replace with -ELGILOY®-- and --PHYNOX®--, respectively.

In the Claims

Please delete claims 1-23 without prejudice.

Please add the following new claims:

24. (New) An implantable medical prosthesis having at least one opening therein and comprising a coating which covers at least a portion of the prosthesis, wherein the coating comprises a polymeric material incorporating a biologically active material, and wherein the average particle size of the biologically active material is equal to or less than about 15 µm and wherein the coating adheringly conforms to the prosthesis to preserve the opening therein when the stent is expanded.

25. (New) The prosthesis of claim 24 wherein the average particle size of the biologically active material is equal to or less than about 10 µm.

26. (New) The prosthesis of claim 24 wherein the coating comprises about 25-45 weight percent of the biologically active material.

27. (New) The prosthesis of claim 24 wherein the biologically active material includes heparin.

28. (New) The prosthesis of claim 24 wherein the polymeric material is a hydrophobic elastomeric material.

29. (New) The prosthesis of claim 28 wherein the elastomeric material is selected from the group consisting of silicones, polyurethanes, polyamide elastomers,

ethylene vinyl acetate copolymers, polyolefin elastomers, ethylene-propylene terpolymer rubbers and combinations thereof.

30. (New) The prosthesis of claim 24 wherein the coating reduces an initial burst release of the biologically active material upon implantation of the prosthesis as compared to a coating comprising the same biologically active material having an average particle size greater than about 15 μm .

31. (New) The prosthesis of claim 24 wherein the prosthesis is an expandable stent having a tubular metal body having open ends and a sidewall structure having openings therein and wherein the coating adheringly conforms to the sidewall structure to preserve the openings therein when the stent is expanded.

32. (New) The prosthesis of claim 31 wherein the stent is a braided stent.

33. (New) An implantable medical prosthesis having at least one opening therein and comprising a coating which covers at least a portion of the prosthesis, wherein the coating comprises a hydrophobic elastomeric material incorporating a biologically active material having an average particle size equal to or less than about 15 μm , wherein the coating reduces an initial burst release of the biologically active material after implantation of the prosthesis as compared to a coating comprising the same biologically active material having an average particle size of greater than about 15 μm and wherein the coating adheringly conforms to the prosthesis to preserve the opening therein when the stent is expanded.

34. (New) The prosthesis of claim 33 wherein the biologically active material includes heparin and the elastomeric material includes silicone.

35. (New) The prosthesis of claim 33 wherein the prosthesis is an expandable stent having a tubular metal body having open ends and a sidewall structure having openings therein and wherein the coating adheringly conforms to the sidewall structure to preserve the openings therein when the stent is expanded.

36. (New) The prosthesis of claim 35 wherein the stent is a braided stent.
37. (New) The prosthesis of claim 33 wherein the coating comprises about 25-45 weight percent of the biologically active material.
38. (New) An expandable stent having a tubular metal body having open ends and a sidewall structure having openings therein, wherein the stent comprises a coating which covers at least a portion of the stent, wherein the coating comprises silicone incorporating heparin, and wherein the average particle size of the heparin is equal to or less than about 15 μm and wherein the coating adheringly conforms to the sidewall structure to preserve the openings therein when the stent is expanded.

REMARKS

Claims 24-38 appear in the present application. Claims 1-23 have been canceled without prejudice. The new claims have been added to more particularly point out and distinctly claim the Applicants' invention. It is believed that no new matter has been added by these amendments. In particular, support for claims 24-38 can be found in the specification at pages 7, 9, 12, 20-21 and in Figures 7 and 8.

Favorable consideration of Applicants' claimed invention is respectfully solicited. No fee is believed due for this Preliminary Amendment. However, should any fee be required, please charge the required amount due to Pennie & Edmonds LLP Account No. 16-1150.

Respectfully submitted,

Date February 4, 2002

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